DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

JUN 25 2010

Report Number: A-09-09-00055

David Maxwell-Jolly, Ph.D.
Director
Department of Health Care Services
1501 Capitol Avenue, MS 0000
Sacramento, CA 95899-7413

Dear Dr. Maxwell-Jolly:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures – Manual Claims*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact Jerry McGee, Audit Manager, at (323) 261-7218, extension 603, or through email at Jerry.McGee@oig.hhs.gov. Please refer to report number A-09-09-00055 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner
Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, IL 60601

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF CALIFORNIA'S INVOICING OF REBATES FOR MEDICAID COMPOUND DRUG EXPENDITURES – MANUAL CLAIMS

Daniel R. Levinson
Inspector General

June 2010
A-09-09-00055

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

In addition to providing mandatory Medicaid services, States may offer certain optional services, such as outpatient prescription drugs, to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program. The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs.

Section 1927(b)(2)(A) of the Act requires States to (1) maintain drug utilization data that identifies, by drug code, the number of units of each covered outpatient drug for which the State reimbursed providers and (2) provide the drug utilization data to manufacturers and CMS. The number of units is applied to the unit rebate amount to determine the total rebate amount due from each manufacturer. States report drug utilization data to manufacturers on a quarterly invoice.

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form. For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.

In March 2010, we issued a report on California's claims for Medicaid compound drug expenditures for fiscal years (FY) 2004 and 2005 (A-09-08-00034). We excluded from that review approximately $15.5 million of hardcopy claims processed manually (manual claims). For those claims, the State agency did not provide ingredient detail because the information was not recorded in electronic format in the State's Rebate Accounting Information System (RAIS).

OBJECTIVE

Our objective was to determine whether the State agency's manual claims for Medicaid compound drug expenditures complied with Federal requirements related to invoicing manufacturers for rebates.

SUMMARY OF FINDINGS

The State agency's $15.5 million of manual claims for Medicaid compound drug expenditures for FYs 2004 and 2005 did not comply with Federal requirements related to invoicing manufacturers for rebates. Specifically, the State agency did not invoice drug manufacturers for or report to CMS the total number of units for compound drug ingredients. Of a random sample of 100 manual claims, 98 claims included ingredients that were eligible for rebates, totaling $4,205 ($2,227 Federal share). Based on our sample results, we estimated that the State agency failed to invoice manufacturers for and collect $2,069,777 ($1,095,964 Federal share) in rebates for eligible compound drug ingredients.

The State agency had inadequate internal controls to ensure that all compound drug expenditures billed on manual claims complied with Federal requirements related to invoicing manufacturers for rebates. The State agency informed us that the RAIS is not currently designed to invoice rebates for compound drug ingredients. In addition, according to State agency guidance, the State agency had not invoiced manufacturers for any compound drug ingredients since the second quarter of 1998.

RECOMMENDATIONS

We recommend that the State agency:

- invoice manufacturers for rebates for the $15.5 million of manual claims for compound drug expenditures and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures;

- invoice manufacturers for rebates for eligible compound drug ingredients billed on manual claims for expenditures for the third quarter of 1998 through FY 2003 and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures; and

- strengthen internal controls, including modifying the RAIS, to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to CMS.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding the first and third recommendations of our draft report, the State agency commented that the rebates will be captured through a system change currently under development, which will allow for invoicing of eligible compound drug ingredients. Regarding the second recommendation, the State agency commented that it would need to assess the feasibility of invoicing rebates for the third quarter of 1998 through FY 2003 because of the large number of resources required to manually review the claims. The State agency's comments are included in their entirety as Appendix C.

We continue to recommend that the State agency invoice manufacturers for eligible compound drug ingredients for the third quarter of 1998 through FY 2003.

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INTRODUCTION

BACKGROUND

Medicaid Program

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements. In California, the Department of Health Care Services (the State agency) administers the Medicaid program.

State Medicaid programs must provide certain medical services, including inpatient and outpatient hospital, physician, and family planning services. States also may offer certain optional services, such as outpatient prescription drugs, as long as the services are included in their approved State plans.

Medicaid Outpatient Prescription Drug Program

All States offer outpatient prescription drugs to eligible Medicaid beneficiaries. Most States, including California, administer their Medicaid prescription drug programs in accordance with the Medicaid drug rebate program.[1] The program generally pays for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. The rebate agreements and related regulations (42 CFR § 447.510) require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. CMS includes these drugs on a quarterly Medicaid drug tape, makes adjustments for any errors, and sends the tape to the States. The tape includes information that the States use to claim rebates from drug manufacturers, including a drug's unit rebate amount. Drugs are identified on the tape by a unique 11-digit numerical code (drug code) that indicates the manufacturer, product, and package size. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement and to calculate the rebates that the manufacturers owe.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by drug code, the number of units of each covered outpatient drug for which the State reimbursed providers. Section 1927(b)(2)(A) of the Act also requires States to provide the manufacturers and CMS with the drug utilization data, not later than 60 days after the end of each rebate quarter. The number of units is applied to the unit rebate amount to determine the total rebate amount due from each manufacturer. States report drug utilization data to manufacturers on a quarterly invoice.

[1] The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program effective January 1, 1991. The program is set forth in section 1927 of the Act. Arizona is the only State that does not participate in the program.

States report drug rebate accounts receivable data on Form CMS-64.9R, Drug Rebate Schedule. This form is part of Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures. The Federal share of drug rebates paid by manufacturers is reported on Form CMS-64 as a reduction to the Federal reimbursement to States for Medicaid expenditures.

Compound Drugs

Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form.[2] For each compound drug claim, CMS guidance states that the drug code and corresponding quantity for each ingredient must be included on the claim for Medicaid reimbursement.[3]

Prior Office of Inspector General Report

In March 2010, we issued a report on California's claims for Medicaid compound drug expenditures for fiscal years (FY) 2004 and 2005.[4] We excluded from that review approximately $15.5 million of hardcopy claims processed manually (manual claims). For those claims, the State agency did not provide ingredient detail because the information was not recorded in electronic format in the State's Rebate Accounting Information System (RAIS).

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency's manual claims for Medicaid compound drug expenditures complied with Federal requirements related to invoicing manufacturers for rebates.

Scope

The audit scope included 49,219 manual claims for compound drug expenditures totaling $15,498,340 ($8,184,656 Federal share) that the State agency claimed for Federal reimbursement for FYs 2004 and 2005 (October 1, 2003, through September 30, 2005). We reviewed a random sample of 100 manual claims totaling $33,272 ($17,617 Federal share).

[2] The U.S. Pharmacopeia provides that "compounding involves the preparation and mixing of one or more components according to a written prescription specifically for individual patients." U.S. Pharmacopeia, *Compounding Backgrounder* (September 2008).

[3] The CMS guidance was published in 72 Fed. Reg. 39217, 39220 (July 17, 2007) in response to a commenter's question about billing of compound drugs.

[4] *Review of Medicaid Compound Drug Expenditures in California for Fiscal Years 2004 and 2005* (A-09-08-00034), issued March 31, 2010.

We limited our internal control review to the State agency's procedures for determining whether compound drugs were eligible for Medicaid coverage and were accurately claimed for Federal reimbursement. We did not review the accuracy or completeness of the quarterly Medicaid drug tapes.

We performed our audit from February to December 2009 and conducted fieldwork at the State agency's offices in Sacramento, California.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and program guidance and the State plan;
- interviewed State agency personnel responsible for identifying, monitoring, and reporting drug expenditures and for reporting rebates;
- confirmed that manufacturers had not been invoiced for compound drug ingredients;
- identified a sampling frame of 49,219 manual claims for compound drug expenditures totaling $15.5 million ($8.2 million Federal share) that the State agency claimed for Federal reimbursement for FYs 2004 and 2005;
- randomly selected 100 compound drug claims totaling $33,272 ($17,617 Federal share) from the sampling frame;
- obtained supporting documentation for each sampled compound drug claim and, for each claim:
    - identified the ingredients (drugs) dispensed and the quantity dispensed;
    - compared the ingredients with drug codes included on the CMS quarterly drug tapes for the period October 1, 1999, through June 30, 2006;
    - calculated rebate amounts that the State agency had not invoiced to manufacturers by multiplying the quantities identified on the claim by the unit rebate amounts contained on the quarterly drug tapes; and
    - calculated the Federal share for rebates that had not been invoiced using the lowest reimbursement rate applicable for each quarter; and
- used the sample results to estimate the total amount and Federal share of the rebates that had not been invoiced for manual claims for compound drug expenditures for FYs 2004 and 2005.

See Appendix A for the sample design and methodology and Appendix B for the sample results and estimates.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

The State agency's $15.5 million of manual claims for Medicaid compound drug expenditures for FYs 2004 and 2005 did not comply with Federal requirements related to invoicing manufacturers for rebates. Specifically, the State agency did not invoice drug manufacturers for or report to CMS the total number of units for compound drug ingredients. Of a random sample of 100 manual claims, 98 claims included ingredients that were eligible for rebates, totaling $4,205 ($2,227 Federal share). Based on our sample results, we estimated that the State agency failed to invoice manufacturers for and collect $2,069,777 ($1,095,964 Federal share) in rebates for eligible compound drug ingredients.

The State agency had inadequate internal controls to ensure that all compound drug expenditures billed on manual claims complied with Federal requirements related to invoicing manufacturers for rebates. The State agency informed us that the RAIS is not currently designed to invoice rebates for compound drug ingredients. In addition, according to State agency guidance, the State agency had not invoiced manufacturers for any compound drug ingredients since the second quarter of 1998.

FEDERAL REQUIREMENTS

Section 1927(b)(1)(A) of the Act states: "A rebate agreement … shall require the manufacturer to provide … a rebate for … covered outpatient drugs of the manufacturer … for which payment was made under the State plan … ."

Section 1927(b)(2)(A) of the Act states that it is the responsibility of the State to "… report to each manufacturer not later than 60 days after the end of each rebate period … information on the total number of units of each [drug code] of each covered outpatient drug dispensed … for which payment was made under the [State] plan during the period, and shall promptly transmit a copy of such report to [CMS]."

Section 1927(b)(1)(B) of the Act states: "Amounts received by a State under [a rebate agreement] … in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance … ."

The CMS *Medicaid Drug Rebate Operational Training Guide*, page E3, states: "Within 15 days after receiving the [unit rebate amount] data tape from CMS, states must submit invoices to each [manufacturer] for any [drug codes] the state reimbursed a pharmacy for during the past quarter."

Furthermore, "… each state must generate a separate record for each [drug code] billed to the [manufacturers] and submit a tape to CMS containing all utilization for the quarter."

REBATES NOT INVOICED FOR COMPOUND DRUG INGREDIENTS

The State agency did not invoice drug manufacturers for or report to CMS the total number of units for compound drug ingredients. Of a random sample of 100 manual claims, 98 claims included ingredients that were eligible for rebates. For the 98 claims, rebates for eligible drugs totaled $4,205 ($2,227 Federal share). The State agency did not collect rebates for or credit the Medicaid program for these eligible drugs.

EFFECT OF REBATES NOT INVOICED

Based on our sample results, we estimated that the State agency failed to invoice for and collect rebates totaling $2,069,777 ($1,095,964 Federal share) for FYs 2004 and 2005. If the State agency had invoiced for and collected the rebates associated with the eligible compound drug ingredients, Federal reimbursement to the State agency would have been reduced by approximately $1.1 million.

INADEQUATE INTERNAL CONTROLS

The State agency had inadequate internal controls to ensure that all compound drug expenditures billed on manual claims complied with Federal Medicaid requirements related to invoicing manufacturers for rebates.

The State agency informed us that the RAIS is not currently designed to invoice rebates for compound drug ingredients. The State agency also informed us that other system projects had taken priority and the resources to implement the system change necessary to invoice rebates for compound drug ingredients were not available.

According to the State agency's *Drug Rebate Section Training Manual*, Medicaid compounds are involved in the drug rebate program; however, "[c]hallenges to the invoicing process resulted in no invoiced compounds after second quarter 1998."

RECOMMENDATIONS

We recommend that the State agency:

- invoice manufacturers for rebates for the $15.5 million of manual claims for compound drug expenditures and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures;

- invoice manufacturers for rebates for eligible compound drug ingredients billed on manual claims for expenditures for the third quarter of 1998 through FY 2003 and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures; and

- strengthen internal controls, including modifying the RAIS, to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to CMS.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Regarding the first and third recommendations of our draft report, the State agency commented that the rebates will be captured through a system change currently under development, which will allow for invoicing of eligible compound drug ingredients. Regarding the second recommendation, the State agency commented that it would need to assess the feasibility of invoicing rebates for the third quarter of 1998 through FY 2003 because of the large number of resources required to manually review the claims. The State agency's comments are included in their entirety as Appendix C.

We continue to recommend that the State agency invoice manufacturers for eligible compound drug ingredients for the third quarter of 1998 through FY 2003.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of hardcopy claims processed manually (manual claims) for compound drug expenditures that the California Department of Health Care Services (the State agency) claimed for Federal reimbursement under the Medicaid outpatient prescription drug program for fiscal years (FY) 2004 and 2005. The State agency claimed a total of $15,498,340 on Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program, and received $8,184,656 in Federal reimbursement.

SAMPLING FRAME

The sampling frame included 49,219 manual claims for compound drug expenditures for which the State agency claimed a total of $15,498,340 and received $8,184,656 in Federal reimbursement under the Medicaid outpatient prescription drug program for FYs 2004 and 2005.

SAMPLE UNIT

The sample unit was an individual manual claim for a compound drug expenditure.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE SIZE

We selected a sample of 100 manual claims for compound drug expenditures.

SOURCE OF THE RANDOM NUMBERS

The source of the random numbers was the Office of Inspector General, Office of Audit Services, statistical software. We used the Random Number Generator for our simple random sample.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the frame from 1 to 49,219. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount and Federal share of rebates that were not invoiced to manufacturers.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

Sample Results

Total Claims in Sampling Frame	Value of Sampling Frame (Federal Share)	Sample Size	Value of Sample (Federal Share)	No. of Claims Without Rebates Invoiced	Value of Rebates Not Invoiced (Federal Share)
49,219	$8,184,656	100	$17,617	98	$2,227

Estimates of Rebates Not Invoiced
(Limits Calculated for a 90-Percent Confidence Interval)

	Total Rebate Amount Not Invoiced	Federal Share
Point estimate	$2,069,777	$1,095,964
Lower limit	1,257,320	665,763
Upper limit	2,882,234	1,526,165

APPENDIX C: STATE AGENCY COMMENTS

DHCS

DAVID MAXWELL-JOLLY
Director

State of California—Health and Human Services Agency
Department of Health Care Services

ARNOLD SCHWARZENEGGER
Governor

MAY 27 2010

Ms. Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services
Office of Inspector General
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The California Department of Health Care Services (DHCS) has prepared its response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG), draft report entitled "Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures – Manual Claims" (A-09-09-00055). DHCS appreciates the work performed by the OIG and the opportunity to respond to the draft report.

Please contact Ms. Traci Walter, Audit Coordinator, at (916) 650-0298 if you have any questions.

Sincerely,

Original Signed By

Toby Douglas
Chief Deputy Director
Health Care Programs

cc: See next page

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Department of Health Care Services
Response to the Office of Inspector General's Draft Report Entitled

Review of California's Invoicing of Rebates for
Medicaid Compound Drug Expenditures – Manual Claims
A-09-09-00055

Recommendation: Invoice manufacturers for rebates for the $15.5 million of manual claims for compound drug expenditures and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures.

Response: The estimated $2.1 million ($1 million Federal funds) in rebates from the $15.5 million in claims for 2004 and 2005 will be captured under the system change currently under development. See response to the third recommendation.

Recommendation: Invoice manufacturers for rebates for eligible compound drug ingredients billed on manual claims for expenditures for the third quarter of 1998 through FY 2003 and refund the Federal share of the rebates collected by reporting it on Form CMS-64 as a reduction to the Federal reimbursement for Medicaid expenditures.

Response: Prior to the end of 2003, Health Care Services' claims system did not capture ingredient information for compound drugs. Rebate invoicing for the third quarter of 1998 through 2003 will require a large number of resources to manually review thousands of claims (as not all necessary data is available on the paper claims) and to input data into the system to determine the rebatable amounts. Changes to the Rebate Accounting and Information System (RAIS) will also be necessary in order to capture the data from the paper claims for rebating purposes. Health Care Services needs to assess the feasibility of this project at this time, particularly in the midst of a transition to a new Medi-Cal Management Information System.

Recommendation: Strengthen internal controls, including modifying the RAIS, to (1) invoice manufacturers for eligible compound drug ingredients and (2) report drug utilization data to CMS.

Response: Health Care Services is in the beginning stages of implementing a system change that will allow for the invoicing of eligible compound drug ingredients. Once implemented, Health Care Services will be able to retroactively invoice manufacturers for claims back to the last quarter of 2003 (September-December). The RAIS system modifications will take an estimated 12 to 16 months.